UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

ATHENEX PHARMA SOLUTIONS, LLC and ATHENEX PHARMACEUTICAL DIVISION, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, Defendants.	Case No. 18-cv-00896-GWC

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, AND ENDO PAR INNOVATION COMPANY, LLC'S MEMORANDUM IN SUPPORT OF MOTION FOR LEAVE TO FILE SUPPLEMENTAL INFORMATION IN SUPPORT OF THEIR MOTION TO DISMISS UNDER FED. R. CIV. P. 12(b)(1)

Defendants request permission to submit the Food and Drug Administration Notice published in the Federal Register on March 4, 2019 (Exhibit A to Brady Affidavit). The Notice removes all doubt that there is no subject matter jurisdiction over Plaintiffs' declaratory judgment case. Simply put, the FDA's determination, published in the Federal Register, means that Plaintiffs cannot sell their "bulk compounded" drug product that they contended gave rise to a case or controversy in this action. While Defendants submit that subject matter jurisdiction never existed in this case, as reflected in Defendants' Motion to Dismiss (ECF No. 10), the FDA's determination destroys any argument that the case has the requisite immediacy to constitute a case or controversy.

Specifically, the FDA yesterday issued a final determination that there is no clinical need for an outsourcing facility (such as Athenex) to compound bulk vasopressin, and thus FDA will not include vasopressin on the 503B Bulks List. Exhibit A, Federal Register 84 No. 42 (Mar. 4, 2019) at 7388. Athenex has admitted that if "vasopressin were removed from the Category 1 [503B Bulks] List, Athenex would be forced to stop selling its vasopressin products." ECF No. 17, Ex. B at ¶ 21. As Athenex is now prohibited from selling its compounded vasopressin products, there is no declaratory judgment jurisdiction and the Court should dismiss this case.

As Par stated in its opening Motion to Dismiss (ECF No. 10-7), it is the bedrock rule of declaratory judgment jurisdiction that a "case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*." *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008) (emphasis in original); *see also MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). The only purported injury or threat of future injury Athenex asserted in its complaint arose from a supposed threat of patent infringement litigation based on "bulk compounded" vasopressin products that Athenex intended to sell. *See* ECF No. 16 at Section III.B and III.C. But in light of the FDA's final determination

(Exhibit A), Athenex cannot sell bulk compounded vasopressin products. Therefore, there is no real and immediate injury or threat of future injury caused by Par. As Athenex readily admits, its redress is with the FDA, not Par. ECF No. 16 at 24 ("Athenex may still bring suit challenging FDA's determination"); *see Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976) ("the 'case or controversy' limitation of Art. III… requires that a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party not before the court"). In fact, Athenex has already filed suit against the FDA, including a motion for a temporary restraining order, in response to yesterday's determination by FDA. Civil Action No. 1:19-cv-00603 (D.D.C.). In its Complaint in that action, Athenex again admits that the FDA's determination means that Athenex cannot sell bulk compounded vasopressin. There is simply no case or controversy here.

For the reasons stated herein and in Par's Motion to Dismiss (ECF No. 10 and 19), the Court should dismiss this case for lack of subject matter jurisdiction.

DATED: Buffalo, New York
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HAGERTY & BRADY

By: s/ Michael A. Brady
MICHAEL A. BRADY, ESQ.
Attorneys for Defendants PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC
69 Delaware Avenue, Suite 1010
Buffalo, NY 14202-3875
Telephone: (716) 856-9443
Fax: (716) 856-0511

Of Counsel:

Daniel G. Brown, Esq.
LATHAM & WATKINS LLP
885 Third Avenue
New York, NY 10022-4834
Telephone: (212) 906-1200
Fax: (212) 751-8464

Jennifer Koh, Esq.
Yi Sun
LATHAM & WATKINS LLP
12670 High Bluff Drive
San Diego, CA 92130
Telephone: (858) 523-5400
Fax: (858) 523-5450